

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Treatment should be continued 24 to 48 hours beyond remission of disease signs, however, not to exceed a total of 4 consecutive days. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 5 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

[68 FR 54805, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004; 73 FR 14926, Mar. 20, 2008]

§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.

§ 522.1662a Oxytetracycline hydrochloride injection.

(a)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella* spp.; *Hemophilus* spp.; *Klebsiella* spp.), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per

pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b)(1) *Specifications.* Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline (as oxytetracycline hydrochloride).

(2) *Sponsor.* See 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Beef cattle and nonlactating dairy cattle—(a) Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale*.

(c) *Limitations.* For 50-milligram-per-milliliter solution, administer intramuscularly or intravenously; for 100-milligram-per-milliliter solution, administer intramuscularly only.

Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 0.5 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 18 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine*—(a) *Amount*. Three to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use*. For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations*. Administer intramuscularly. Do not inject more than 5 milliliters per site. Do not use for more than 4 consecutive days. Discontinue treatment at least 26 days before slaughter.

(c)(1) *Specifications*. The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle and nonlactating dairy cattle. It is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Hemophilus spp.*, *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*,

bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, acute metritis, and wound infections caused by staphylococcal and streptococcal organisms.

(ii) It is administered to cattle at a dosage level of 3 to 5 milligrams per pound of body weight per day. It may be administered intramuscularly or intravenously from a 50 milligram per milliliter solution. It is administered intravenously from a 100 milligram per milliliter solution. Severe foot-rot and the severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight. Treatment should be continued 24 to 48 hours following remission of disease symptoms, however, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 hours, consult a veterinarian. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the amount injected at each site according to the size of the animal. For very small calves do not use more than 2 milliliters per injection site.

(iii) Not for use in lactating dairy cattle. Discontinue treatment at least 19 days prior to slaughter. When administered intramuscularly within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site and surrounding tissues.

(d)(1) *Specifications*. The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) In beef cattle and nonlactating dairy cattle as follows:

(a) It is used for the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Hemophilus spp.*; foot-rot and diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms.

(b) Administer by intravenous or intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and severe forms of the indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended.

(c) If the labeling of the drug bears the statement "Federal law restricts this drug to use by or on the order of a licensed veterinarian," it may include additional directions for use in beef cattle and nonlactating dairy cattle for the treatment of anaplasmosis caused by *Anaplasma marginale*, and anthrax caused by *Bacillus anthracis* in which case the drug is given at 3 to 5 milligrams of oxytetracycline per pound of body weight per day for anthrax, and at 5 milligrams per pound of body weight per day for anaplasmosis.

(ii) In swine as follows:

(a) It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. Administered to sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(b) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day to swine. Administered to sows at 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after farrowing.

(iii) In poultry (broilers, turkeys, and breeding chickens) as follows:

(a) It is used for the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli*; fowl cholera caused by *Pasteurella multocida*; infectious sinusitis caused by *Mycoplasma gallisepticum*; and infectious synovitis caused by *Mycoplasma synoviae*.

(b) Administered subcutaneously to chickens 1 day to 2 weeks of age at 6.25 milligrams of oxytetracycline per bird per day diluted with 1 part of the drug to 3 parts of sterile water; to chickens 2 to 4 weeks of age using the same diluted product at 12.5 milligrams of oxytetracycline per bird; to chickens 4 to 8

weeks of age without dilution at 25 milligrams of oxytetracycline per bird; to chickens 8 weeks of age (broilers and light pullets) at 50 milligrams of oxytetracycline per bird; to adult chickens at 100 milligrams of oxytetracycline per bird.

(c) Administered subcutaneously to turkeys 1 day to 2 weeks of age and 2 to 4 weeks of age at the same dosage as chickens; to turkeys 4 to 6 weeks of age at 50 milligrams of oxytetracycline as the undiluted product per bird; to turkeys 6 to 9 weeks of age at 100 milligrams of oxytetracycline per bird; to turkeys 9 to 12 weeks of age at 150 milligrams of oxytetracycline per bird; to turkeys 12 weeks of age and older at 200 milligrams of oxytetracycline per bird. In light turkey breeds, no more than 25 milligrams per pound of body weight is administered. For the treatment of infectious sinusitis in turkeys, $\frac{1}{4}$ to $\frac{1}{2}$ milliliter of the drug is injected directly into each swollen sinus depending upon the age of the bird and the severity of the condition. At the time that the sinuses are treated, the drug should also be administered subcutaneously to the birds according to the dosage schedule given in paragraph (d)(3)(iii)(c) of this section. If refilling of the sinuses occurs, the treatment may be repeated in 5 to 7 days.

(iv) Treatment of all diseases should be instituted early. Treatment should continue for 24 to 48 hours beyond the remission of disease symptoms, but not exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, diagnosis and therapy should be reevaluated.

(v) When injecting intramuscularly in adult livestock, do not inject more than 10 milliliters at any one site. The volume administered per injection site should be reduced according to age and body size so that 1 or 2 milliliters are injected in smaller animals such as small calves and young pigs. Intravenous administration is recommended in cattle when daily dosage exceeds 50 milliliters.

(vi) Treatment must be discontinued at least 5 days prior to slaughter for chickens and turkeys and at least 22 days prior to slaughter for cattle and swine. When administered intramuscularly to animals within 30

days of slaughter, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

(vii) Not for use in lactating dairy animals. Do not administer to laying hens unless the eggs are used for hatching only.

(e)(1) *Specifications*. Each milliliter of sterile solution contains 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(a) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use*. Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(c) *Limitations*. Administer intramuscularly. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 1 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the

withdrawal time. Discontinue treatment at least 15 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine*—(a) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, administered once, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use*. For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infections enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations*. Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine, reducing the volume according to age and body size to 1 to 2 milliliters in young pigs. Discontinue treatment at least 22 days prior to slaughter.

(f) [Reserved]

(g)(1) *Specifications*. Each milliliter of sterile solution contains 100 milligrams of oxytetracycline as oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use*. The drug is used for the treatment of diseases due to oxytetracycline-susceptible organisms as follows:

(i) *Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*—(a) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day.

(b) *Indications for use*. For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Hemophilus* spp., or *Klebsiella* spp.

(c) *Limitations*. Administer by intramuscular, intravenous, or subcutaneous injection. In severe forms of the indicated diseases, administer 5 milligrams of oxytetracycline per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 48 hours, consult a veterinarian. Do not

inject more than 10 milliliters per injection site intramuscularly in adult cattle; no more than 1 milliliter per site in calves weighing 100 pounds or less. Do not slaughter cattle for 13 days after intramuscular or intravenous treatment, or 2 days after subcutaneous treatment. Exceeding the highest recommended dosage or duration of treatment (not more than 4 consecutive days) may result in residues beyond the withdrawal period. A withdrawal period has not been established for use of this product in prurminating calves. Do not use in calves to be processed for veal.

(ii) *Swine*—(a) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use*. For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: As an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations*. Administer intramuscularly. If no improvement is noted within 24 hours, consult a veterinarian. Do not inject more than 5 milliliters per site. Discontinue treatment at least 20 days prior to slaughter.

(h)(1) *Specifications*. Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsors*. See No. 054628 in § 510.600(c) of this chapter for use of 50 and 100 milligrams per milliliter solution; and Nos. 000859 and 055529 in § 510.600(c) for use of 100 milligrams per milliliter solution.

(3) *Conditions of use*—(i) *Amount*. The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of severe forms of the indicated diseases.

(ii) *Indications for use*. The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and calf diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; wound infections, acute metritis, and traumatic injury caused by staphylococcal and streptococcal organisms.

(iii) *Limitations*. Administer 50-milligram-per-milliliter solution intramuscularly; administer 100-milligram-per-milliliter solution intravenously. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less, do not inject more than 2 milliliters intramuscularly per site. Discontinue treatment at least 22 days before slaughter. Not for use in lactating dairy animals.

(i)(1) *Specifications*. Each milliliter of sterile solution contains 50 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: Administer 3 to 5 milligrams of the oxytetracycline hydrochloride intramuscularly per pound of body weight per day.

(ii) *Indications for use*. The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations*. In severe forms of the indicated diseases, administer the

equivalent of 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. In adult livestock, do not inject more than 10 milliliters at any one site. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less inject only 2 milliliters per site. Discontinue treatment at least 18 days before slaughter. Not for use in lactating dairy cattle.

(j) [Reserved]

(k)(1) *Specifications*. Each milliliter of sterile solution contains either 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount*. 3 to 5 milligrams per pound of body weight daily, 5 milligrams per pound for anaplasmosis, severe foot rot, and severe forms of other diseases.

(ii) *Indications for use*. Treatment of diseases due to oxytetracycline-susceptible organisms as follows: pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; acute metritis and wound infections caused by staphylococcal and streptococcal organisms; if labeled for use by or on the order of a licensed veterinarian, it may be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations*. Administer by intravenous injection. Treatment should be continued 24 to 48 hours following remission of disease symptoms, but not to exceed a total of 4 consecutive days. If no improvement occurs within 24 to 48 hours, reevaluate diagnosis and therapy. Discontinue use at least 19 days prior to slaughter. Not for use in lactating dairy cattle.

[40 FR 13853, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1662a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.1662b Oxytetracycline hydrochloride with lidocaine injection.

(a) *Specifications*. The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride and 2 percent lidocaine in each milliliter of sterile aqueous solution.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated for use in the treatment of diseases of dogs caused by pathogens sensitive to oxytetracycline hydrochloride including treatment for the following conditions in dogs caused by susceptible microorganisms: Bacterial infections of the urinary tract caused by *Hemolytic staphylococcus*, *Streptococcus* spp., Bacterial pulmonary infections caused by *Brucella bronchiseptica*, *Streptococcus pyogenes*, *Staphylococcus aureus*, secondary bacterial infections caused by *Micrococcus pyogenes* var. *albus*, *Brucella bronchiseptica*, *Streptococcus* spp.

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983; 79 FR 16192, Mar. 25, 2014]

§ 522.1664 Oxytetracycline and flunixin.

(a) *Specifications*. Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as amphoteric oxytetracycline and 20 mg flunixin base as flunixin meglumine.

(b) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.286 and 556.500 of this chapter.

(d) *Conditions of use cattle*—(1) *Amount*. Administer once as an